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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,094	01/03/2001	Mark S. Humayun	55534 (71699)	4130

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EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/754,094	Applicant(s) HUMAYUN ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21-35 and 39-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-19,21-23,25-35* is/are rejected.

7)☐ Claim(s) *5-7,24 and 39-57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 12-16, 19, 21-23 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al (US Pat# 6,355,027) in view of applicant's own disclosure.

Le discloses a flexible microcatheter system having a flexible cannula (16) with a proximal end and a distal end. The system also has a second cannula (14) having a larger diameter than the flexible cannula and is less flexible (1:46-49). The second cannula has a proximal end and a distal end and a portion of the flexible cannula is housed within the distal end of the second cannula (see figures 1-3). The second cannula forms a fluid tight seal and mounted about the flexible cannula (see figure 3; the mounting of cannula 14 and 16 within proximal connector 12 must be fluid tight between all three components in order to prevent leaking). The proximal end of the second cannula is sized for attachment (connector 12) to the tip of a syringe.

Regarding the function language in claims 1-4, 16, 25-33 that generally provide for the functioning of the microcatheter or cannula as a hands free injection system. The examiner reminds applicant that function language in device claims is given little patentable weight. As long as the prior art device meets the structural limitations of the claims and is capable of performing the claimed function then the prior art reads on the claims.

In the claims above, the instant invention is a device that injects into the retinal vein of the eye for periods of time from at least 5 min to 2 hours using no support systems to hold the device in position and provides an infusion flow rate of 0.2 cc/min through the proximal end of the second cannula. The prior art is capable of performing this function due to the fact that it is a microcatheter for use in small and tortuous vascular paths and is made from flexible materials.

Additionally, while Le fails to disclose a modified microcannula system having a silicone plug with a central aperture applicant's own disclosure renders this claim limitations obvious. Page 10 of the instant application states that "microcannula are well known" and "the general features...may be in accordance with conventional catheters". Furthermore, silicone plugs with central apertures (otherwise known in the art as hemostatic valves) are well known in the cannula art and used for maintaining bodily fluids within the body when a larger cannula punctures the body and another instrument is inserted through the larger cannula.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-11 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le. Le meets the claim limitations as described above but fails to include the cannula being made from polyimide and having the flexible cannula and second cannula dimensions of claims 9-11 and 17-18 .

At the time of the invention it would have been obvious to make the cannula from a material such as polyimide since the catheter is disclosed as having flexible properties and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The motivation for using a medical grade plastic such as polyimide would have been in order to reduce the incidence of allergic reaction of the skin to contact with non-medical grade plastic materials.

Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Castora (US Pat# 5947296). Le meets the claim limitations as described above but fails to include a kit including one or more of the catheters packed in sterile conditions.

Castora discloses a catheter kit with multiple catheters packaged in one kit. See figures.

At the time of the invention, it would have been obvious to package the catheter of Le as per the organization of Castora since packaging catheters is well known and considered inherent in the art if the catheter is planned for human use.

Allowable Subject Matter

Claims 5-7 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 39-57 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 1/23/04 have been fully considered but they are not persuasive.

Applicant argues that the Le reference fails to teach or suggest all of the claimed invention. Generally, (i) it is argued that Le's device is used differently then the claimed invention and therefore based on this use will have a different structure and properties, (ii) the flexibility of the Le device does not match the flexibility of the claimed invention, and (iii) Le does not have a second cannula as taught and claimed.

To support applicant's argument regarding the differences in use of the two devices resulting in structural/property differences, applicant states that the instant invention is not pushed like the Le device but instead is "inserted into the retinal vein an amount sufficient for it to be secured in the retinal vein to prevent unwanted dislodgement". This feature of the instant invention is not in the claim language. Applicant is reminded that limitations from the specification are not read into the claims. Also functional language is not given significant

patentable weight if the claimed structure is capable of performing the recited function (i.e. the claimed function and not functions from the specification).

Applicant argues that the flexibility of instant invention is different from the flexibility of the Le device. It is noted that the features upon which applicant relies (i.e., "Applicant's catheters must be very flexible along their lengths so that any movement is absorbed by the flexibility of the catheter") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The term flexible is a broad term and reviewed broadly.

Applicant states that the strain relief cannula of Le is not a second cannula. It is noted that the features upon which applicant relies (i.e., "the inner diameter of the second cannula transfers the solution to the flexible cannula and into the retinal vein") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant also relies on that the second cannula is an intraocular part of the microcatheter placed in the eye which is also not recited in the claims.

Regarding the arguments to claims 8-11 and 17-18, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the arguments to claims 34-35, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the outstanding objection to claims 39-57, independent claim 39 was incorrectly amended into allowable form. In the office action dated 1/24/03, claim 39 was rejected under 112 2nd and indicated as having allowable subject matter if amended to overcome the 112 rejection AND to include all of the limitations of the base claim and any intervening claims. See office action. Claim 39, at the time, depended from any one of claims 1-3. When it was amended claim 39 did not include all of the limitations from any one of those claims. Applicant merely placed the claim in independent form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams
May 1, 2004

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700